

patients (mean age 65 years, mean Deyo-Charlson Comorbidity Index 0.6, mean hospital length of stay 6.35 days); 214 cases and 214 controls were randomly selected from the cohort for chart data analysis. In the 12 months post-index arthroplasty, there were 830 (2.5%) patients who had SSI, 644 (1.9%) who had SSB, and 84 (0.3%) who developed VTE. Of all SSI events, 65% occurred by 90 days following arthroplasty. Significantly more patients who had received post-discharge thromboprophylaxis versus those that did not developed SSI but not SSB (SSI: 28.4% vs 23.2% [ $P<0.0001$ ]; SSB: 28.5% vs 23.3% [ $P=0.07$ ]). In the logistic regression analysis, only the duration of surgery ( $P=0.004$ ), surgical revision ( $P=0.04$ ), and rehospitalization ( $P<0.001$ ) emerged as independent predictors of SSI. **CONCLUSIONS:** Post-discharge thromboprophylaxis and SSB were not associated with post-operative SSI, thus dispelling concerns about the increased risk of developing SSI due to prolonged SSB associated with the use of pharmacologic thromboprophylaxis. Additional studies are needed to endorse these findings in similar patient populations.

#### PCV4

##### THROMBOPROPHYLAXIS AND THE RISK OF POST-DISCHARGE VENOUS THROMBOEMBOLISM AND BLEEDING IN PATIENTS UNDERGOING TOTAL HIP OR KNEE ARTHROPLASTY

Huo MH<sup>1</sup>, Spencer DL<sup>2</sup>, Fan Y<sup>2</sup>, Borah BJ<sup>3</sup>, Mills RM<sup>4</sup>, Klaskala W<sup>4</sup>  
<sup>1</sup>University of Texas Southwestern Medical Center, Dallas, TX, USA, <sup>2</sup>OptumInsight, Life Sciences, Eden Prairie, MN, USA, <sup>3</sup>Division of Health Care Policy and Research, Mayo Clinic, Rochester, MN, USA, <sup>4</sup>Janssen Research & Development, LLC, Raritan, NJ, USA

**OBJECTIVES:** The risk of post-discharge venous thromboembolism (VTE) and bleeding in total knee and hip arthroplasty (TKA/THA) has not been completely elucidated because interventions to reduce these adverse outcomes have evolved rapidly. The objective of this study was to determine the incidence of these events and associated risk factors, and to evaluate the use of thromboprophylaxis. **METHODS:** Administrative medical records (2004–2009) from a large healthcare plan were linked to an inpatient database of 450 hospitals in the United States. Adult patients undergoing TKA or THA with no evidence of prior orthopaedic surgeries, prior VTE, post-discharge revision surgeries, or death were included. ICD-9-CM diagnosis and CPT/HCPC procedure codes were used for evaluating symptomatic VTE and bleeding rates 90 days post-surgery. Multivariate analyses were performed to identify predictors of VTE and bleeding after hospitalization. **RESULTS:** Two hundred twenty-six of 9167 patients (2.5%; 3109 THA, 6058 TKA) with a median age of 60 years and a mean Charlson-Quan comorbidity index score of 0.5 experienced VTE, and 324 (3.5%) had bleeding. Most of these events occurred post-discharge (70% and 79%, respectively). Over 50% of VTE occurred within 30 days post-discharge. Consistent predictors of VTE and bleeding after hospitalization were inpatient VTE or bleeding, respectively, and all-cause rehospitalization. Post-discharge thromboprophylaxis was not a significant risk factor for bleeding. Ninety-eight percent of patients received thromboprophylaxis during hospitalization; 26% received it post-discharge. During hospitalization, three-fourths of patients received enoxaparin and/or warfarin, often in combination with mechanical prophylaxis devices (57%). Post-discharge, mean antithrombotic drug exposure was 7.4 days. **CONCLUSIONS:** Patients who experience VTE or bleeding during hospitalization and patients who are rehospitalized are at greatest risk of thromboembolic and bleeding outcomes, respectively, post-discharge. These data also suggest that the use of thromboprophylaxis following hospitalization should not significantly increase the risk of post-discharge bleeding after TKA/THA.

#### PCV5

##### INTRA-ARTERIAL THROMBOLYSIS VERSUS STANDARD TREATMENT OR INTRAVENOUS THROMBOLYSIS IN ADULTS WITH ACUTE ISCHEMIC STROKE: A SYSTEMATIC REVIEW AND META-ANALYSIS

Nam J, He J, O'Reilly D  
 PATH Research Institute, McMaster University, Hamilton, ON, Canada

**OBJECTIVES:** Recent evidence has suggested that intra-arterial thrombolysis (IAT) may provide benefit beyond intravenous thrombolysis (IVT) in ischemic stroke patients. Previous meta-analyses have only compared IAT to standard treatment [without thrombolysis]. The objective was to review the benefits and harms of IAT in ischemic stroke patients. **METHODS:** EMBASE, MEDLINE, the Cochrane registry and the stroke trials registry were queried from inception to 2011. Two reviewers independently screened titles and abstracts for randomized controlled trials of ischemic stroke comparing IAT to either IVT or standard treatment. Primary outcomes included good functional outcome, excellent functional outcome, mortality and symptomatic intracranial hemorrhage. Results were stratified by comparison treatment. **RESULTS:** A total of 543 citations were identified. Two trials ( $n=81$ ) compared IAT to IVT while the remaining four trials ( $n=351$ ) compared IAT to standard treatment. IAT increased good functional outcome by 47% when compared to standard treatment (RR=1.47; 95%CI=1.07-2.22;  $I^2=0$ ) and 74% when compared to IVT (RR=1.74; 95%CI=1.01-3.01;  $I^2=0$ ). Excellent functional outcome was 73% higher with IAT when compared to standard treatment (RR=1.73; 95%CI=1.17-2.57;  $I^2=0$ ) and not significantly different when compared to IVT (RR=1.74; 95%CI=0.85-3.56), though only one trial reported results for the latter. IAT did not increase mortality when compared to standard treatment (RR=0.82; 95%CI=0.56-1.21;  $I^2=0$ ) or IVT (RR=1.12; 95%CI=0.47-2.68;  $I^2=0$ ). Symptomatic intracranial hemorrhage, however, was almost 4 times higher with IAT when compared to standard treatment (RR=3.90; 95%CI=1.41-10.76;  $I^2=0$ ) while not significantly different when compared to IVT (RR=1.13; 95%CI=0.32-3.99;  $I^2=42\%$ ). **CONCLUSIONS:** Compared to standard treatment, IAT increases good and excellent functional outcomes; compared to IVT, IAT increases good functional outcome. As well, IAT does not increase mortality over IVT or standard treatment. However, IAT increases symp-

tomatic intracranial hemorrhage compared to standard treatment while the risk remains comparable to IVT. Imprecise pooled estimates for good and excellent functional outcome prevent any overtly strong recommendation for the use of IAT.

#### PCV6

##### RISK OF ADVERSE CARDIOVASCULAR OUTCOMES ASSOCIATED WITH CONCOMITANT USE OF CLOPIDOGREL AND PROTON PUMP INHIBITORS IN ELDERLY MEDICARE BENEFICIARIES

Mahabaleshwarkar R, Yang Y, Datar M, Bentley JP, Strum M, Banahan BFI, Null KD  
 University of Mississippi, University, MS, USA

**OBJECTIVES:** Evidence regarding the effect of concomitant use of clopidogrel and proton pump inhibitors (PPIs) on adverse cardiovascular outcomes remains inconclusive. The purpose of the current study was to examine the effect of concomitant use of clopidogrel and PPI in a national sample of elderly Medicare beneficiaries (age  $\geq 65$  years). **METHODS:** The study used a nested case-control design. A cohort of Medicare beneficiaries taking clopidogrel for any period between July 1, 2006 and December 31, 2008 was identified from a 5% national sample of Medicare claims data using prescription records. Beneficiaries who had a gap of more than 30 days between clopidogrel fills were excluded. Within the continuous clopidogrel user cohort, cases [beneficiaries who experienced a major adverse cardiovascular event (MACE, composite of acute myocardial infarction, coronary artery bypass graft, percutaneous coronary intervention, stroke, and mortality)] and controls (beneficiaries who did not experience a MACE) were identified from inpatient and outpatient claims. Concomitant use of clopidogrel and PPI was ascertained using prescription drug records. Each case was matched to a control on age and time to start clopidogrel using a greedy match algorithm. Conditional logistic regression was conducted on the matched sample to evaluate the association between concomitant use and occurrence of a MACE. **RESULTS:** A cohort of 43,159 clopidogrel users was identified. 15,722 of them (36.4%) used clopidogrel and PPI concomitantly at any time during the study period. 9,332 cases were identified and matched to equal number of controls. Beneficiaries using clopidogrel and PPI concomitantly were more likely to experience a MACE as compared to beneficiaries receiving clopidogrel only (odds ratio: 1.411, 95% Confidence Interval: 1.322 – 1.506). **CONCLUSIONS:** Concomitant use of clopidogrel and PPI was associated with an increased risk of experiencing a cardiovascular adverse event. Caution should be exercised when co-prescribing the two medications to elderly patients.

#### PCV7

##### IMPACT OF COMORBIDITIES ON RISK OF CARDIOVASCULAR HOSPITALIZATION AMONG PATIENTS WITH AND WITHOUT ATRIAL FIBRILLATION

Panaccio M<sup>1</sup>, Cummins G<sup>2</sup>, Miao R<sup>1</sup>, Davis P<sup>1</sup>, Wentworth C<sup>3</sup>, Lanes S<sup>3</sup>, Reynolds M<sup>3</sup>, Michels S<sup>2</sup>, Koren A<sup>1</sup>  
<sup>1</sup>Sanofi-Aventis, Bridgewater, NJ, USA, <sup>2</sup>Quintiles Global Consulting, Hawthorne, NY, USA, <sup>3</sup>United BioSource Corporation, Lexington, MA, USA

**OBJECTIVES:** To quantify the impact of atrial fibrillation (AF) and major AF comorbidities on risk of cardiovascular (CV) hospitalization (CVH). **METHODS:** This retrospective cohort study assessed an administrative claims database (Thomson Reuters' MarketScan) for newly diagnosed AF patients and demographically matched non-AF patients to characterize risk of comorbidities and CVH among AF patients. Patients aged  $\geq 40$  years with  $>364$  days in the database were identified by a qualifying AF diagnosis ( $\geq 2$  outpatient diagnoses within 30 days of each other or  $\geq 1$  inpatient diagnosis) from January 1, 2004 to June 29, 2009. **RESULTS:** A total of 210,524 patients were included (mean age  $74.0 \pm 12.5$  years, 49% male, 68% Medicare). Compared with non-AF patients, AF patients were more likely prescribed beta blockers (44% vs. 22%), digoxin (15% vs. 2%), and anticoagulants (29% vs. 2%); had a higher severity of illness (Charlson Comorbidity Index score  $\geq 4$ : 16.5% vs. 4.1%); and had higher comorbidity prevalence (odds ratio; 95% confidence interval): myocardial infarction (13.1; 11.7-14.7), heart failure (HF; 9.2; 8.9-9.6), and pulmonary embolism (8.2; 7.2-9.5). Risk of new CV events and comorbidities at follow-up was significantly ( $P<0.0001$ ) higher in AF patients, most notably major bleeding, HF, valvular disease, and stroke. AF patients with baseline comorbidities related to CHADS<sub>2</sub> (score  $\geq 2$ ) or CHA<sub>2</sub>DS<sub>2</sub>-VASc (score  $\geq 4$ ) experienced  $\geq 2.5$ -fold higher rates of overall CVH. AF patients had 3.4-fold higher CVH risk with  $\sim 30\%$  hospitalized at 1 year vs. 8% of non-AF patients; 24.3% of AF patients experienced recurrent AF requiring hospitalization (incidence: 176/1000 person-years). **CONCLUSIONS:** AF patients have higher burden of baseline CV comorbidities that portend greater risk of CVH and new CV comorbidities following diagnosis compared to matched non-AF patients. These data indicate AF recurrence requiring hospitalization and overall hospitalizations 1 year following diagnosis is common.

#### PCV8

##### IMPACT OF COMORBIDITIES ON TIME IN THERAPEUTIC RANGE IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION

Choi JC<sup>1</sup>, Damaraju C<sup>2</sup>, Mills RM<sup>2</sup>, Wildgoose P<sup>3</sup>, Fields L<sup>3</sup>, Schein J<sup>1</sup>, Nelson WW<sup>1</sup>  
<sup>1</sup>Janssen Scientific Affairs, LLC, Raritan, NJ, USA, <sup>2</sup>Janssen Research & Development, LLC, Raritan, NJ, USA, <sup>3</sup>Janssen Pharmaceuticals, Inc., Raritan, NJ, USA

**OBJECTIVES:** Time in therapeutic range (TTR) may be a quality indicator for anticoagulation. Previous studies have demonstrated that heart failure (HF) and other comorbidities are associated with poorer anticoagulation control; however, this association was not studied in a representative US population. The objective was to determine the association between HF, other comorbidities, patient characteristics, and TTR among patients with nonvalvular atrial fibrillation (NVAF). **METHODS:** We analyzed longitudinal patient-level anticoagulation management records collected between 2006 and 2010 by decision support software, Coag-Clinic™. Adult patients with NVAF who used warfarin over 12 months with no gap  $>60$  days between visits were identified. The Rosendaal method was used to cal-